

EXHIBIT E

DEPOSITION OF

RUSSELL F. DUNN, PH.D., P.E.

Taken on behalf of the Defendants

March 7, 2016

1 RUSSELL F. DUNN, PH.D., P.E.

2 was called as a witness, and after having been
3 first duly sworn, testified as follows:

4

5 EXAMINATION BY MR. DAVIS:

6 Q. Good morning, Dr. Dunn.

7 A. Good morning.

8 Q. Since we've met before, I'll just kind
9 of jump into things. Let me hand you first, to
10 start off, a copy of Exhibit 1.

11 (Whereupon Exhibit 1 was marked as an
12 exhibit.)

13 BY MR. DAVIS:

14 Q. And can you just confirm that that's a
15 copy of your report that is the subject matter of
16 this deposition?

17 A. Yes, sir.

18 Q. Okay. Let me just run through a couple
19 more documents.

20 Well, why don't you just keep -- yeah,
21 we'll --

22 A. Oh. Sure.

23 Q. I realize you've got your own notebook
24 with your copy.

25 A. Uh-huh.

1 configuration.

2 BY MR. DAVIS:

3 Q. Okay. Can you explain how Prolift+M
4 differs from Prosima?

5 MR. BOWMAN: Object to the form.

6 BY MR. DAVIS:

7 Q. And if it's the same answer, that's
8 fine.

9 A. Oh, the Prolift+M has Monocryl filament
10 in it, also, in addition to the polypropylene.

11 Q. And what is the significance of the
12 Monocryl?

13 A. It's biodegradable.

14 Q. Okay. As I read your report, I -- I
15 see a number of references to ISO 14971.

16 Do you recall that?

17 A. Yes, sir.

18 Q. And were there any other medical
19 industry specific standards that you relied upon in
20 your report other than ISO 14971?

21 A. I specifically dealt with the ISO 14971
22 and insofar as it references other standards that
23 it relies upon.

24 Q. Okay. Well, are you aware that
25 ISO 14971 does cite a number of other standards?

1 A. Absolutely, I'm aware of that.

2 Q. And I'm just trying to understand. Did
3 you go -- did you have any occasion to go review
4 any of those other standards that are cited in
5 ISO 14971?

6 A. I may have reviewed some of those
7 standards. Not -- they were not the subject of my
8 report. I specifically dealt with 14971.

9 Q. Okay. And let me just follow up.

10 You may or may not recall that, at your
11 last deposition, I asked you some questions about
12 ISO 10993 and its various subparts.

13 Do you recall that generally?

14 A. Yes. Biocompatibility, yes, sir.

15 Q. Have you had any occasion since your
16 last deposition to review any portions of
17 ISO 10993?

18 A. That's -- no, sir. That's not my area
19 of expertise, is biocompatibility.

20 Q. Okay. Do you -- do you know what all
21 the subject matter of biocompatibility encompasses?

22 MR. BOWMAN: Object to form.

23 BY MR. DAVIS:

24 Q. Well, I mean, I understand it's not
25 your expertise.

1 MR. BOWMAN: Object to form.

2 BY MR. DAVIS:

3 Q. Do you have an opinion as to how long
4 Prolene mesh needs to be in the body before it
5 doesn't matter whether it has some degradation?

6 MR. BOWMAN: Object to form.

7 THE WITNESS: That's not the subject of
8 my report.

9 BY MR. DAVIS:

10 Q. Do you know of any harm associated with
11 the oxidative degradation of Prolene used in the
12 pelvic floor?

13 A. All I know is how the properties of the
14 polymer change. And that's the subject of my
15 report. And that it gets hard and embrittled as it
16 oxidizes.

17 Q. Well, but the subject of your report is
18 also FMEAs and risk analysis, right?

19 A. It is FMEAs.

20 Q. And you understand that, in order to
21 call something a hazard, which you've done -- well,
22 let's back up.

23 You -- throughout your report, you call
24 Prolene mesh in the body a hazard, correct?

25 A. I say that it should be evaluated for

1 potential failure modes.

2 Q. Well, now, let me ask you. I mean --
3 well, you agree your report repeatedly says that
4 Prolene used in a mesh in the pelvic floor is a
5 hazard?

6 A. It readily oxidizes, yes. And
7 that's -- and that is a defect.

8 Q. But your opinion is that it is a
9 hazard, correct?

10 A. Yes.

11 Q. Okay. And you understand -- according
12 to ISO 14971, you understand the definition of a
13 hazard, correct?

14 A. Yes.

15 Q. What is that definition?

16 A. A potential source of harm.

17 Q. Okay. So please identify the harm that
18 you have associated with oxidative degradation of
19 polypropylene in order to allow you to call it a
20 hazard.

21 A. You're -- I'm telling you that it gets
22 hard and it gets embrittled, and I'm also
23 indicating that, as a potential failure mode, it
24 has to be fully evaluated by Ethicon relative to
25 its harm.

1 Q. As -- as you sit here today, do you
2 know of any harm that you can tell the Court that's
3 associated with what you describe as Prolene being
4 a hazard?

5 A. I know the changes in the polymer
6 itself, that it becomes cracked and embrittled and
7 hard.

8 Q. Okay. My question is, can you -- can
9 you identify any specific harm today?

10 A. That it's changing the properties
11 inside the body over time.

12 Q. Do you understand the definition of
13 "harm"? What does "harm" mean?

14 MR. BOWMAN: Object to form.

15 THE WITNESS: Physical injury or damage
16 to the health of people or damage to the property
17 or the environment.

18 BY MR. DAVIS:

19 Q. Okay. Can you tell me any injury to
20 the person in whom the mesh is implanted?

21 A. That's not the subject of my report.

22 Q. Okay. Yet -- so you've -- you've
23 labeled Prolene mesh in the pelvic floor as a
24 hazard, but you have not been able to associate
25 that hazard with any specific harm?

1 it works, and then I'll hand it over.

2 MR. DAVIS: Okay.

3 BY MR. DAVIS:

4 Q. In the meantime, Dr. Dunn, I've handed
5 you Exhibit 6, and my first question is, can you
6 tell us whether this is a document that you
7 considered as part of your analysis?

8 A. It could be. I don't know.

9 Q. Well --

10 A. I don't have every document memorized.

11 Q. Okay.

12 A. And I've looked at documents over the
13 last two years.

14 Q. Okay. Let me put it this way: In your
15 report, at various points you say that it's your
16 opinion that Ethicon failed to consider oxidative
17 degradation, correct?

18 A. That is correct.

19 Q. So did -- if -- did you make any effort
20 to look at Exhibit Number 6 and -- and distinguish
21 it or to justify an opinion that we're not
22 considering oxidative degradation?

23 A. I am justifying that opinion based on
24 the failure mode and effects analysis. This is not
25 the failure mode and effects analysis. If they

1 considered oxidative degradation, it will be in
2 their failure mode effects and analysis.

3 If you want to show me a failure mode
4 and effects analysis that has a line item of
5 oxidative degradation, then they considered it.
6 Otherwise, they did not consider it. If it's not
7 in the FMEA, it was not considered.

8 Q. Okay. So -- have you ever heard of a
9 biocompatibility risk assessment?

10 A. Not a specific biocompatibility risk
11 assessment. The ISO 10- -- 14971 includes
12 biocompatibility. It considers that -- it's
13 inclusive of that in the risk assessment.

14 Q. Okay.

15 A. You don't have separate risk
16 assessments for different matters. When we talk
17 about the overall risk assessment of a product, it
18 all has to be within ISO 14971.

19 (Whereupon Exhibit 7 was marked as an
20 exhibit.)

21 BY MR. DAVIS:

22 Q. Let me hand you Exhibit 7.

23 A. Yes, sir.

24 Q. Do you see the first page of this
25 exhibit has a title "Essential Requirements

1 oxidative degradation of Prolene in the pelvic
2 mesh, once it's in the body, has any practical
3 consequence?

4 A. I don't know what Ethicon's evaluation
5 of that was because it was not included in their
6 FMEA. You're asking me to do what they should have
7 done, and I'm telling you that I want to look at
8 how they view that and how they judge that risk,
9 and it's not part of their analysis.

10 Q. I hear you. But --

11 A. It's absent.

12 Q. Yeah. And -- I hear you. But now --
13 listen very carefully to my question.

14 A. Yes.

15 Q. I just want a "yes" or "no," and then
16 you can explain.

17 Do you know whether there is any
18 practical consequence to oxidative degradation of
19 Prolene in the Prolene meshes that are the subject
20 of your report once they're in the body?

21 A. That's -- that's not part of my report.
22 I know the consequences on the polymer properties
23 itself, and I've not extended that to the effect in
24 the human body.

25 Q. So is the answer to my question "yes"

1 Q. Okay. And so it says in Section 4.1,
2 the first sentence, quote, Risk analysis shall be
3 performed for the particular medical device as
4 described in 4.2 to 4.4, unquote.

5 Did I read that correctly?

6 A. Yes.

7 Q. Okay. And notice that, under that
8 Section 4.1, it has a series of notes.

9 Do you see that series of notes?

10 A. Yes.

11 Q. Notes 1 through 4 and --

12 A. Yes.

13 Q. Look at Note Number 4. Do you see it
14 says, quote, Additional guidance on risk analysis
15 techniques for toxicological hazards is given in
16 Annex I, unquote.

17 A. Sure.

18 Q. Did I read that correctly?

19 A. Yes.

20 Q. Okay. So you're familiar with Annex I?

21 A. I've seen Annex I, sure.

22 Q. Okay. And so -- you've turned to
23 Annex I?

24 A. Yes.

25 Q. Do you see it has a title, "Guidance on

1 Risk Analysis Process for Biological Hazards"?

2 That's the title?

3 A. Yes.

4 Q. Okay. And then what standard does it
5 cite the reader to for the general principles for
6 the biological evaluation of materials and medical
7 devices?

8 A. For biological hazards, it's 10993, as
9 I indicated previously.

10 Q. Well, it didn't say biological hazard;
11 it says "biological evaluation," doesn't it?

12 A. That -- that sentence says that. But
13 it's under Annex I, which is the guidance on risk
14 analysis process for biological hazards.

15 Q. Okay. You don't think it has anything
16 to do with chemical hazards?

17 A. I -- let's address that. Go back to
18 Table E.1, page 51.

19 Q. Sure.

20 A. I specifically indicated that those are
21 examples of hazards. You should see in the second
22 column there is a heading called "Biological." It
23 is not the same heading as "Chemical."

24 I told you before that degradation
25 products is under chemical; it's not under

1 biological, nor is it under biocompatibility.

2 So let's don't confuse the two.

3 Q. So what standard does the ISO refer you
4 to -- to -- for guidance on chemical hazards?

5 A. There -- there isn't one. You need
6 chemical expertise. You need polymer expertise.
7 There's no one standard for chemical analysis.

8 Q. Okay. Let's turn back to Annex I for a
9 second.

10 A. Okay. I'm there.

11 Q. Look at Section 1.2.1. And do you see
12 where that section reads in part, quote, The
13 biological risk analysis should take account of,
14 and then it lists four bullet points, correct?

15 A. Uh-huh.

16 Q. The first bullet point is "The physical
17 and chemical characteristics of the various choices
18 of materials."

19 Do you see that?

20 A. Yes.

21 Q. And do you see on down in Section
22 1.2.2, it specifically includes, among the analysis
23 of biocompatibility, the influence of
24 biodegradation, correct?

25 A. It does.

1 Q. Okay. So will you now agree that
2 ISO 10993 does, in fact, address such matters as
3 how you do a risk analysis to look at oxidative
4 degradation?

5 A. I will not.

6 Q. Okay. So --

7 A. And I disagree totally.

8 Q. Okay. So your opinion is that Annex I
9 has nothing to do with analyzing oxidative
10 degradation?

11 A. I'm saying -- I'm saying that Annex I
12 does not necessarily include oxidative degradation.
13 It is more -- more concerned with biocompatibility
14 and toxicity of chemical constituents and those
15 types of matters.

16 Q. Okay. Well, what does it mean when it
17 says -- when it says in 1.2.2, your risk analysis
18 should include the, quote, chemical nature of the
19 materials, unquote?

20 A. Where -- where are you?

21 Q. Look at the heading for Section 1.2.2,
22 "Chemical Nature of the Materials."

23 Is it your testimony that you don't
24 think that includes the possibility of oxidative
25 degradation?

1 A. The intent is to say that they -- that
2 Ethicon has not performed a risk analysis on
3 oxidative degradation.

4 Q. Yeah. And so let me ask you this.
5 Look on down to the third paragraph on that page.

6 A. Uh-huh.

7 Q. The second sentence. Says, quote, An
8 important consideration in the acceptability of a
9 residual risk is whether an anticipated clinical
10 benefit can be achieved through the use of
11 alternative design solutions or therapeutic options
12 that avoid exposure to that risk or reduce the
13 overall risk, unquote.

14 Did I read that correctly?

15 A. Yes.

16 Q. Okay. And, again, I just want to make
17 sure I've covered this -- well, first, do you agree
18 that that is an important consideration?

19 A. Yes.

20 Q. Okay. And have you considered that in
21 any of your work on this case?

22 A. That's not what I'm doing. I'm
23 assessing whether or not Ethicon has performed a
24 risk/benefit analysis.

25 Q. Okay.

1 A. And the problem is -- and you're not
2 asking me this question -- and I know why --
3 Ethicon can't do a risk/benefit analysis because
4 they haven't evaluated the risk. So it's kind of
5 hard to do a risk/benefit analysis when you don't
6 evaluate the risk first.

7 Q. Okay.

8 A. And my assessment is to look at what
9 Ethicon has done, not to perform that for them.

10 Q. Okay. Thank you.

11 Turn on page 39 of ISO 14971.

12 A. Yes.

13 Q. Do you see they have a section on "Risk
14 Evaluation and Risk Acceptability"?

15 A. Yes.

16 Q. Are you familiar with that section?

17 A. Yes.

18 Q. Okay. So you do -- you do understand
19 that one important consideration when you're
20 evaluating risk is to have an understanding of what
21 the state of the art is?

22 A. Yes.

23 Q. Okay.

24 A. Yes.

25 Q. And, again, you don't have an

1 understanding of what the state of the art is for
2 these pelvic floor mesh devices, do you?

3 MR. BOWMAN: Object to form.

4 THE WITNESS: That's not the purpose
5 of -- of my report.

6 BY MR. DAVIS:

7 Q. Well, so do you or don't you?

8 A. I understand different methodologies,
9 but that's not the subject of my report.

10 Q. Okay.

11 A. And I guess I'll point out, since
12 oxidative degradation risk was not assessed, I
13 can't tell how Ethicon viewed that potential
14 failure mode relative to the current state of the
15 art.

16 Q. I meant to cover one more thing with
17 you back there on page 44.

18 A. Yes, sir.

19 Q. Are you familiar with Section D.6.3,
20 "Criteria for Risk/Benefit Judgments"?

21 A. Yes.

22 Q. Okay. Do you see where it says, quote,
23 Those involved in making risk/benefit judgments
24 have a responsibility to understand and take into
25 account the technical, clinical, regulatory,

1 A. Not recently.

2 Q. Which ones did you read?

3 A. I can't tell you as I sit here today.

4 Q. I mean, you're aware that some of these
5 folks had depositions of -- like up to six or seven
6 different days? Are you aware of that?

7 A. Yes.

8 Q. And did you take any of these people
9 and look at all their depositions?

10 MR. BOWMAN: Object to form.

11 THE WITNESS: I've looked at some
12 depositions. I can't recall which ones exactly
13 that I've looked at.

14 BY MR. DAVIS:

15 Q. Well, in connection with forming your
16 opinions on whether or not Ethicon has support for
17 its belief that oxidative degradation is not an
18 issue, I mean, did you try to look at any
19 depositions --

20 A. It is unnecessary. If it was
21 considered, it will be in the FMEA. Bottom line.
22 Doesn't matter who testified about it. They can
23 say whatever they want to. If it's not in the
24 FMEA, it was not considered.

25 Q. Okay. What if it's in the risk

1 analysis that is referenced in the FMEA? Does that
2 mean they considered it or does it mean they did
3 not consider it?

4 A. Are you talking about the device design
5 safety assessment?

6 Q. I want to go back to Exhibit 10, yes.

7 A. Okay.

8 Q. Question Number 10 again.

9 A. You're talking about a question.
10 You're not talking about an actual analysis.
11 You're talking about a question.

12 Okay. Go ahead.

13 Q. You see it refers you to the Gynemesh
14 PS design history file as support for their answer
15 that they have considered the biocompatibility.

16 A. Yes.

17 Q. Okay. So, if that reference takes you
18 to a risk assessment for the biocompatibility that
19 includes oxidative degradation, then you would have
20 to stand corrected?

21 A. No.

22 Q. Oh. Okay.

23 A. You don't have to go and fight through
24 the weeds to figure out what's been done as an
25 adequate safety analysis. I teach failure mode and

1 effects analysis. It will be listed on the
2 document if it's considered.

3 Q. Are you telling the jury that ISO 14971
4 does not allow reference to other documents?

5 A. That's not what I said.

6 Q. Okay.

7 A. I said, if it's considered as a
8 potential failure mode, it will be listed on the
9 failure mode and effects analysis. And of course
10 it references other documents. But, if it was
11 considered as a potential failure mode, it will be
12 listed on the FMEA.

13 Q. Can you explain --

14 A. There's no if, ands, or buts about it.

15 Q. Can you explain to the Court the
16 meaning of the word "biocompatibility" as it
17 relates to ISO 10993?

18 MR. BOWMAN: Object to form.

19 THE WITNESS: No. I will relate it to
20 ISO 14971.

21 BY MR. DAVIS:

22 Q. Well, I'm not asking you about that
23 ISO. I'm asking you about 10993. We'll talk about
24 that one -- other one in a minute.

25 A. ISO 14971 references ISO 10993, and

1 Q. Have you ever prepared a -- or been on
2 a team that was preparing an FMEA for a medical
3 device?

4 A. No. No --

5 Q. Making it easier --

6 A. -- I've not been on a team. I've --
7 I've led teams on hundreds of FMEAs and -- and
8 teach FMEAs, but I've not been on a particular team
9 that's performing that for a medical device.

10 Q. But have you ever been on a team
11 preparing a biocompatibility risk assessment under
12 ISO 10993?

13 A. That's -- that's not my area of
14 expertise.

15 Q. Okay. Do you know how to evaluate a
16 biocompatibility risk assessment according to
17 the -- to determine its compliance with the
18 ISO 10993 standards?

19 A. That's not the subject of my report.

20 Q. Is that because in part it's beyond
21 your expertise?

22 A. That is not my expertise -- I wouldn't
23 say it's beyond my expertise; that's not my
24 expertise.

25 Q. That's fair enough.

C E R T I F I C A T E

STATE OF TENNESSEE)
COUNTY OF DAVIDSON)

I, Lise S. Matthews, RMR, CRR, CRC, LCR
353, Licensed Court Reporter and Notary Public, in
and for the State of Tennessee, do hereby certify
that the above deposition was reported by me, and
the transcript is a true and accurate record to the
best of my knowledge, skills, and ability.

I further certify that I am not related to nor an employee of counsel or any of the parties to the action, nor am I in any way financially interested in the outcome of this case.

I further certify that I am duly licensed by the Tennessee Board of Court Reporting as a Licensed Court Reporter as evidenced by the LCR number and expiration date following my name below. I further certify that this transcript is the work product of this court reporting agency and any unauthorized reproduction and/or transfer of it will be in violation of Tennessee Code Annotated 39-14-104, Theft of Services.

IN WITNESS WHEREOF, I have hereunto set
my hand and affixed my notarial seal this _____
day of _____, 2016.

Lise S. Matthews, RMR, CRR, CRC
LCR 353 Expiration Date 6/30/2016
Notary Public Commission Expires
March 6, 2018

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